FDA review of e-cigarettes is as critical as ever—any delay must be brief

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After years of harmful delays by the FDA, a federal judge last July set a May 12, 2020, deadline for e-cigarette manufacturers to apply to the FDA and demonstrate a public health benefit in order to keep their

products on the market. This deadline also applied to other tobacco products regulated under a 2016 FDA rule, including certain cigars. Now the FDA has asked the court for a 120-day extension of this deadline, to September 9, 2020, because of the coronavirus (COVID-19) outbreak.

As plaintiffs in the lawsuit that resulted in the May 12 deadline, our organizations are deeply concerned about the harmful impact of further delays in the FDA's review of e-cigarettes, cigars and other tobacco products on our nation's children and health. While we do not intend to formally oppose the FDA's current request due to the extraordinary circumstances of the COVID-19 pandemic, any extension should be brief, and tobacco companies cannot be allowed to use this public health emergency to continue avoiding their legal obligation to submit their products for FDA review. FDA review is more critical than ever in light of skyrocketing youth use of e-cigarettes and mounting concerns that smoking and vaping may increase risk of severe complications from COVID-19. Now is not the time to leave products like e-cigarettes on the market with zero review of their health impact.

As the FDA itself stated last week, "People with underlying health issues, such as heart or lung problems, may have increased risk for serious complications from COVID-19. This includes people who smoke and/or vape tobacco or nicotine-containing products. E-cigarettes can damage lung cells."

In addition, tobacco companies have no one but themselves to blame if they are not ready to submit their applications. They have known that they would have to file these applications since at least May 2016, when the FDA issued its final rule to begin regulating e-cigarettes and other previously unregulated tobacco products, and they have known of the May 12 deadline since July 2019, when the deadline was set by U.S. District Judge Paul W. Grimm. As Judge Grimm wrote, "the record offers little assurance that, in the absence of a deadline for filing, the

industry will do anything other than raise every roadblock it can and take every available dilatory measure to keep its products on the market without approval."

Even if the application deadline is extended, the FDA must also continue to enforce its new policy that cleared the market of pod-based e-cigarettes like Juul, except for menthol and tobacco flavors, and take action to remove other flavored e-cigarettes that appeal to kids, as it has promised to do. There is nothing to stop the FDA from taking immediate action to remove flavored products like the disposable and refillable e-cigarettes that have quickly become popular with kids.

In setting the May 12 deadline, Judge Grimm acted in a lawsuit filed by the American Academy of Pediatrics and its Maryland chapter, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids, Truth Initiative and five individual pediatricians. Our health groups are being represented by the legal staff of the Campaign for Tobacco-Free Kids, lawyers at Democracy Forward Foundation and the law firm of Brown, Goldstein & Levy.

Provided by American Heart Association